



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Prior Approval of Meat and Poultry Product Labels

THE FSIS MANDATE

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) ensures that meat and poultry products sold in interstate commerce are safe, wholesome, and accurately labeled. Based on traditional standards of what constitutes a meat or poultry food product, FSIS is responsible generally for products containing a minimum of over 3 percent fresh meat or 2 percent or more cooked poultry. The Food and Drug Administration (FDA) monitors most other foods sold interstate.

FSIS carries out its responsibilities through: the inspection of animals before slaughter; in-plant inspection of meat and poultry slaughter and processing; approval of meat and poultry product formulas and labels before the products are marketed; ongoing plant inspection of these products; and monitoring of meat and poultry products through distribution channels.

PRIOR APPROVAL OF LABELS

The prior approval of product labels is a critical regulatory function because, in effect, it licenses the producer to market an approved product with an approved label.

THREE CATEGORIES OF LABELING

The prior approval system offers three categories for processing labels. Two of them -- generic approvals and inspector-in-charge (IIC) approvals -- are designed as timesavers. Previously approved labels in which certain minor changes are made may be considered generically approved. Labels involving slightly more difficult, but still routine, issues can be submitted for IIC approval. This cuts the time it takes to approve the average label from roughly 10 days when labels are mailed to Washington, to less than an hour. In more detail, the three prior approval categories are:

1) "Generic Approval" - This method covers minor changes to previously approved labels. A generic label needs no specific approval, and requires only that management submit a copy of that label to the plant inspector-in-charge (IIC) before putting it into use.

2) IIC Approval - Many routine new labels and label changes can be approved by the plant inspector-in-charge.

3) Headquarters Approval - Labels involving complex or novel issues, labels for which preliminary or "sketch" approval is desired, all labels for imported products, and all requests for temporary label approval must be sent to Washington, DC.

Use of generic and IIC approval is voluntary, however, and a plant can refer any label to Washington.

FSIS Facts

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FLOW CHART, FORMS IN APPENDIX

For details on how label applications move through the three categories in the prior approval process, see The Label Flow Chart on p. 8. Page 9 is the instruction sheet for label application Form 8822-1; page 10 is Form 8822-1.

SUBMITTING A LABEL FOR PRIOR APPROVAL

Whether a company decides to submit a label to the plant IIC or send it to the Standards and Labeling Division (SLD) in Washington, DC, an application form (preferably FSIS Form 8822-1) must be completed for each sketch or final label to be submitted. The exceptions are labels that fall in the generically approved category. For generically approved labels, the company need only provide a copy of the modified label with its former approval number to the IIC before beginning to use it.

COMPLETING THE APPLICATION FORM

FSIS Form 8822-1, available from the USDA area office or through the plant IIC, requires that the applicant supply:

- * The Product Name - Give the common or usual name that describes the food. In many cases, this will be the name used for all products meeting a product standard. "Chili con carne" is an example. Other names will be unique to the manufacturer's product.

- * The USDA plant or establishment number for the location where the product will be made.

- * For imports, ports of entry must be named. Also, labels printed in a foreign language must be accompanied by an English translation.

- * Area of Principal Display Panel - Include the dimensions of the panel in square inches.

- * Product Formula - List all ingredients in the product, ranked from most to least by weight. To protect the manufacturer, FSIS has formally declared that the product formula or "recipe" is the exclusive property of the manufacturer and exempt from mandatory disclosure under the Freedom of Information Act.

- * Processing Procedures - Describe all procedures used to make the product. Be sure to indicate type of container -- can, casing, retortable pouch, where applicable.

- * Packer's name and address, including zip code.

- * Signatures - The application should be signed by a plant representative and by the IIC.

- * Use - State precisely for what type of product and on what type of container the label will be used. For example, will the label be used for institutional or retail-sale type product? And will it be used on shipping or consumer-size containers?

For further instructions, see p. 9, "Instructions for Preparation of FSIS Form 8822-1."

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WHAT LABEL REVIEWERS LOOK FOR

Generally reviewers, whether at the plant or headquarters, check sketches and final labels to make sure they describe a safe, wholesome product that follows the composition and processing standards defined for meat or poultry products using that name. They also check to make sure the information on the label is truthful, accurate, and easy to understand.

The Meat and Poultry Products Inspection Regulations, the Inspection Manual, and the "Labeling Policy Book," a compilation of official decisions over the years, are the reviewer's daily guides. In addition, labeling policy memos document new or significant policy decisions. (The Policy Book and memos are available from the FSIS Printing and Distribution Section, USDA, Room 0151-S, Washington, DC 20250.)

Reviewing a sketch or final label application item by item, reviewers check to see that all applicable parts of the form are complete. They also verify that the label contains the required label elements:

- * The product name.
- * An ingredient statement for products with two or more ingredients.
- * The USDA inspection legend.
- * The firm name and address, including the two-letter State abbreviation and zip code. This could be the manufacturer, packer, or distributor.
- * A "keep frozen" or "keep refrigerated" statement, if necessary.
- * A net weight statement, when necessary.

Looking at label illustrations, reviewers verify that the artwork accurately reflects the product. For example, if the label photo shows four slices of meat, there must be at least four slices in the container. Also, if the label shows a garnish of parsley and tomatoes not included in the product, the picture must be qualified by a phrase such as "serving suggestion."

GETTING SKETCH APPROVAL

When you want sketch approval, submit an application (preferably Form 8822-1) in triplicate to SLD in Washington, DC. Attach a copy of the sketch to each application form. The sketch itself can be a printer's proof or other version which clearly shows all the required label elements (p. 3) plus their size, location, and an indication of final color.

The sketch is then ready to be mailed. Wait for sketch approval from Washington before ordering the final label from the printer.

MAILING ADDRESS

Mail the sketch application to: Benjamin Franklin Station
P.O. Box 7416
Washington, DC 20044

All correspondence on label approvals -- final label applications, too -- should be sent to the Ben Franklin Station address.

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MISTAKES TO AVOID IN PREPARING A LABEL

The following are common errors or deficiencies that can cause a sketch or final label to be disapproved:

1. Product name incomplete or unacceptable.
2. Product name not shown with required prominence.
3. One or more required labeling features not shown with acceptable prominence.
4. All required labeling information not shown on principal display panel.
5. Firm name and address not shown as authorized for each establishment.
6. If packed for another firm, failure to precede the firm name and address with "Packed For" or "Distributed By."
7. Ingredients statement does not match the formula shown on the application form.
8. Ingredients not listed by their true names.
9. List of components not preceded by the word "Ingredients" followed by a colon.
10. Inspection legend not exact duplication of illustration shown in the meat and poultry regulations. If the legend is larger or smaller than the official size, all elements of it must be adjusted proportionally.
11. Net weight not shown with correct size and spacing as required by the regulations.
12. When catch weight is used, not showing "net weight ___ lbs. oz.," or any indication on the application form that the net weight statement will be subsequently applied.
13. Illustration not representative of contents.
14. Label design or colors are misleading as to product quality or character.
15. A statement such as "Serve as Illustrated" is not shown when ingredients other than the product itself are illustrated.
16. It is a mistake to submit lithographed cans themselves. Submit colored paper takeoffs of the litho-label.

DECIDING WHAT CATEGORY TO USE

To use the prior approval system to advantage, companies must be familiar with the three label categories. This guide should help. The plant IIC can also assist in deciding what category is best for a particular label or group of labels.

EASY GENERIC APPROVAL

The following minor changes to previously approved labels can be treated as "generically" approved. Just provide the IIC with a copy of the label and its previous approval number before starting to use it.

- * A change in the wording or arrangement of opening or serving instructions.
- * Reductions or enlargements of previously approved labels.
- * Change only in the type of packaging material the label is printed on.
- * Addition of pictures of holiday rabbits, Santas, etc., that do not obscure mandatory information.

- * The addition, deletion or amendment of a coupon, a cents-off statement, cooking instructions, packer product code information, or the Universal Product Code.
- * Changes in the company name or address in the signature line.
- * Changes in the net weight - for instance, when a 1-pound package is reissued as a 2-pound package.
- * The addition or deletion of open dating information.
- * The addition, deletion, or amendment of recipe or serving ideas.
- * Changes in punctuation and substitutions of abbreviations for words - "lb." for "pound," or vice versa.
- * Newly assigned or revised establishment numbers for a particular plant.
- * Application of the name and address of the distributor to a previously approved master or stock label from which it had been omitted.

IN-PLANT IIC APPROVAL

The following routine new labels or label changes can be approved by the IIC:

- * Labels that have been approved in mockup or sketch form by the SLD Washington staff, if the final label is prepared without any changes, or with only those minor changes specified in this list or in the preceding generic category.
- * Simple labeling for a product with only one ingredient -- such as "Chicken Drumsticks" or "Lamb Chops" -- as long as it does not make any special claims, involve a foreign language, or make any guarantees.
- * Labeling for products sold to the Federal Government on contract.
- * Labels for shipping containers carrying fully labeled products.
- * Labels for products not intended for use as human food, such as animal foods or pharmaceuticals.
- * Meat and poultry inspection legends.
- * Ink brands and hot brands used on meat food products.
- * Inserts, tabs, and similar labeling material that contain no reference to the product name.
- * Labels for poultry heads and feet for export.

If a label can be IIC-approved, complete the application form in triplicate, attaching a copy of the label to each copy of the form. Submit the application to the IIC. If it meets the appropriate standards, the IIC will return an approved copy to the submitter, keep a copy for his or her own files, and send the third copy to headquarters to be audited and become part of FSIS's permanent label files.

LABELS THAT MUST BE APPROVED AT HEADQUARTERS

While companies can submit any label to SLD reviewers at headquarters, the only labels that must go to headquarters are those for sketch and temporary approval, those for imported products, and those involving complex or novel issues, such as labels not previously approved which make a quality guarantee or nutrition claim.

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For labels to be sent to headquarters, as for those submitted to the IIC, three copies of the application form are necessary. Attach a copy of the label to each form.

For multiplant corporations seeking SLD label approval for more than one plant, include an additional copy for forwarding to each plant IIC.

Four copies of the application form are required for foreign labels, plus an additional copy for each port of entry, appropriate ministry and producing plant.

When submitting a previously approved label for approval of a new modification, include the original approval number for that label.

Send the application to: Benjamin Franklin Station, P.O. Box 7416, Washington, DC 20044.

No additional information should be included in this address. An "Attention" line actually slows the distribution of incoming labels. If a label is to be submitted to a specific person, that name should appear on a memo attached directly to the application itself, inside the mailing envelope.

PRODUCT SAMPLES

For products for which there are no published or informal USDA standards, SLD may request that a sample be submitted with the application. Samples are reviewed to assure that both product and label are acceptable. To avoid the possibility of spoilage or delay, arrange a mailing schedule that will get the samples to Washington during the workweek.

Mail product samples to: Standards and Labeling Division
FSIS MPITS
Room 204, Agriculture Annex Bldg.
Washington, DC 20250

HAND-CARRIED LABELS

In addition to the availability of generic and IIC-approval, management still has the option of hand-carrying labels to Washington. Where possible, hand-carried applications are reviewed within 24 hours of receipt.

APPEALS OF DISAPPROVED LABELS

A company can appeal the disapproval of any label, whether it comes from an IIC or the Washington staff. Plant inspectors, however, do not have the authority to process appeals. A company must appeal to SLD in Washington. If the appeal is denied at any level from the reviewer through the director in SLD, it can be pursued through the Deputy Administrator of MPITS (Meat and Poultry Inspection Technical Services), the Administrator of FSIS, USDA's Administrative Law Judge, USDA's Judicial Officer, and the Federal courts.

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TEMPORARY LABEL APPROVALS

The granting of temporary label approvals is another area of authority reserved for SLD Washington staff.

Temporary approval for labels that may be deficient in some manner may be granted only under certain conditions: 1) the label is accurate; 2) the company would suffer economic hardship if the approval were not granted; 3) no unfair competitive advantage would be conferred on the grantee; and 4) the interim label poses no health, safety, or dietary threat to consumers.

Temporary approvals may not exceed 6 months. However, in unusual cases, an extension can be granted if a company can show that intervening circumstances have made it impossible to correct the label problems in the first 6-month period, and the continued use of the temporary label poses no consumer hazard.

FOR MORE INFORMATION

For further details on label approval, write or call: The Standards and Labeling Division, Meat and Poultry Technical Services, U.S. Dept. of Agriculture, Washington, DC 20250.
Phone: 202/447-6042.

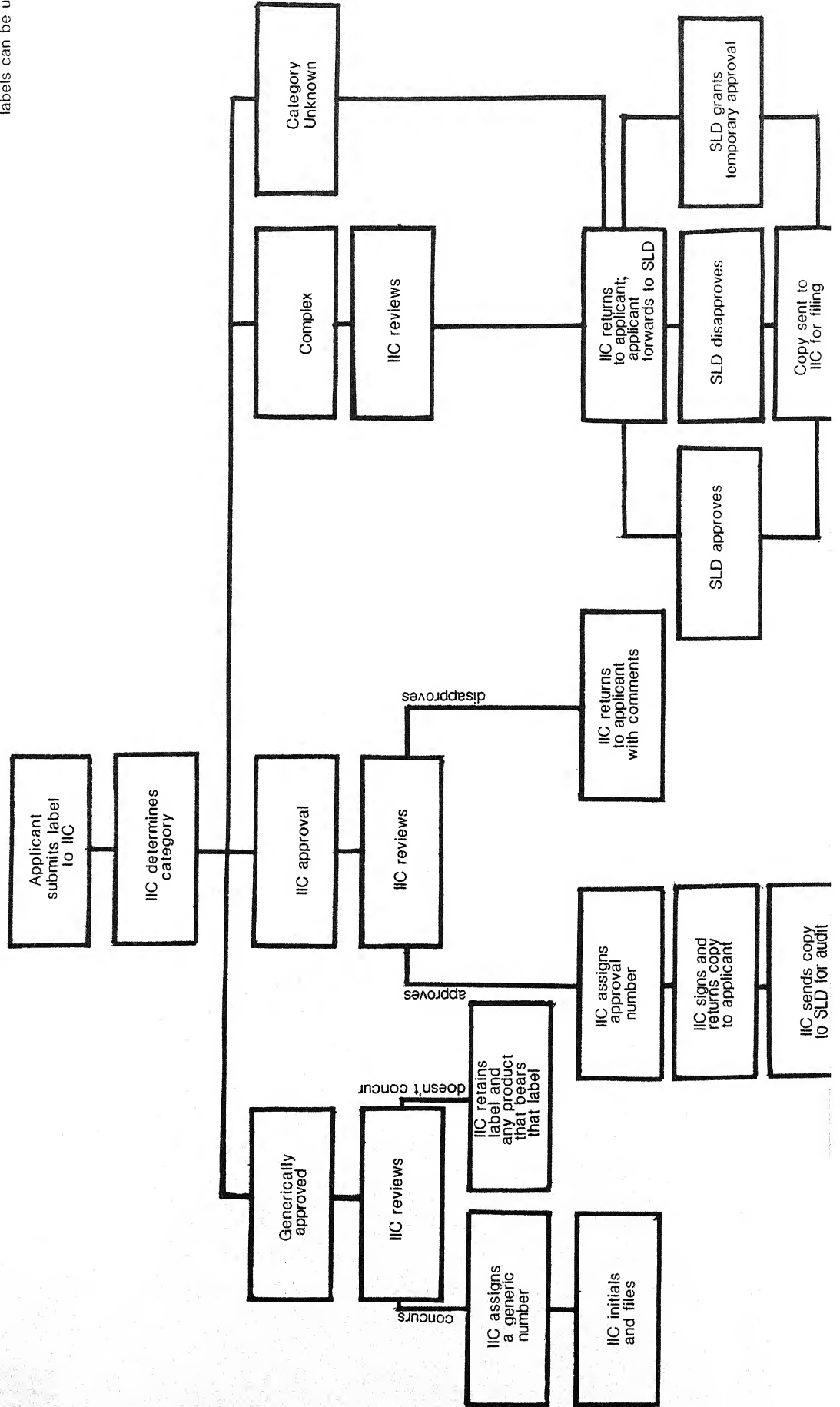
(Supersedes FSIS-11, "FSIS Facts: Prior Approval of Meat and Poultry Products and Their Labels," January 1982.)

Chart

IIC: Inspector-in-Charge at plant
 SLD: Standards and Labeling Division,
 Washington Headquarters reviewers

Generically approved labels:

Category needing, no specific approval except that a copy must be given to the IIC before these labels can be used.



INSTRUCTIONS FOR PREPARATION OF FSQS FORM 8822-1

(For additional information, see *Inspectors' Manual*)

A. PREPARATION OF APPLICATION

- Submit an original and 2 copies for each label application.
- Add 2 copies for each additional plant for which approval is requested (*Type name and address of each plant on Item 10*)
- Add 1 copy for each additional address to which this form is to be sent. (*Type name and address on Item 10*)
- Add 1 copy for firm's records
- **Import Labels:**
 - Add 1 copy for each port of entry;
 - 1 copy for appropriate Ministry;
 - 1 copy for each producing plant.

B. SUBMISSION OF LABELS

Sketches: Self-explanatory.

Finals and Temporaries: Actual label or color litho take off to be used.

Photocopies or "xerox" copies not acceptable.

Quantity to Submit: Same as application (see above).

C. FOREIGN LANGUAGE

Labels printed in foreign languages must be accompanied by English language translation.

D. ASSEMBLY OF APPLICATION

Staple, with 1 staple only, page 1, page 2, etc., one copy each. Staple all copies of label to the back of application forms. If only page 1 is used, staple all copies together. Use as few staples as possible. (*Do not use paper clips*).

E. MAIL COMPLETE APPLICATION TO: Post Office Box 7416
Benjamin Franklin Station
Washington, D.C. 20044

THE FOLLOWING INSTRUCTIONS RELATE TO NUMBERED ITEMS ON FORM

1, 2 & 3 Leave blank, for USDA use only.

4. ESTABLISHMENT OR PLANT NUMBER AND/OR PORTS OF ENTRY

Import Labels: Enter ports of entry for which approval is requested.

5. NAME OF PRODUCT. Use common or generic product name, i.e., "Frankfurter, Cereal Added" or "Meat Patties in Gravy." (*Do not use trade brand names or coined names, such as "Joe's Corn Dogs" or "Joe's Sloppy Joes."*) Do not use trade or brand names. If coined names such as "Corn Dogs" are used, also show true product name, such as "Batter wrapped Wiener."

6. ACTION REQUESTED BY USDA

If temporary approval, insert number of days requested and number of labels on hand. If final approval, indicate if there is a previous sketch approval.

7. STATE AREA IN SQUARE INCHES

The principal display panel is the entire side of the package to which the label is affixed. See regulations 317.2(d) and 381.116(b).

8. PRODUCT FORMULA

Poultry Products, follow regulation 381.133. Meat Products, list the ingredients by percent or weight in order of their predominance. If product consists of several components, e.g. a frozen dinner, list each component separately and indicate the percentage or amount of each component in the product. If additional space is needed attach a continuation sheet.

Check whether weight or percent is used. It is preferred percentages be used, and the total must equal 100 percent. If weights are used, show in pounds, kilograms or grams. (*No gallons, pints, cups, teaspoons, etc.*) The total must equal the weights of the individual units. (*Example: Crust + Cheese + Sauce + Meat = Total new weight of unit.*)

DO NOT use fractions. Express as decimals carried to two places. Example: 1-1/4 lbs., show as 1.25 lbs. Example: 3/4 lbs., show as .75 lbs.

9. PROCESSING PROCEDURES

Poultry Products, follow regulation 381.133. Meat products, indicate any process limited by regulation. Examples of processes to be indicated are:

- a. Sectioning chopping or grinding and then reforming.
- b. refrigeration and or freezing product.
- c. trichina treatment.
- d. cooking temperatures for cooked beef or roast beef.
- e. method of preparing barbeque products.
- f. method of injecting or infusing liquids into products.
- g. method of preparing hams, corned beef, pastrami, and like cured products.
- h. smoking procedure
- i. method of preparing pizza toppings.
- j. cooking temperatures for product labeled cooked.

10. NAME AND ADDRESS OF FIRM

Insert Firm's name and mailing address. Use 2 letter symbol for State. Show postal zip code. (*Domestic Labels. If you wish copies of this form to be sent to other Firm's addresses, enter these addresses on the copies to be sent to them. Copies will be sent only to addresses provided. Also see A above for preparation of form.*)

11. SIGNATURE OF APPLICANT OR AGENT To be signed by the applicant or agent representing the official establishment or plant.

12. SIGNATURE OF INSPECTOR Signed by the designated USDA inspector after reviewing for completeness and compliance with applicable regulations.

13. Leave blank, for USDA use only. (*Any condition, modification or remarks applied to the application when approved are conditions governing use of the approved devices.*)

1.	2.	3.	4. ESTABLISHMENT OR PLANT NO. AND/OR PORTS OF ENTRY	5. NAME OF PRODUCT	7. AREA OF PRINCIPAL DISPLAY PANEL
ED BY USDA FOR APPROVAL					
Information previously approved as a sketch? <input type="checkbox"/> Yes <input type="checkbox"/> No					
New, date of sketch					
for instructions.					

<input type="checkbox"/> TEMPORARY		<input type="checkbox"/> REQUEST FOR EXTENSION	
Prior approval number		Number of labels on hand	
Number of days requested		Number of days requested	
PCT <input type="checkbox"/> WEIGHT (No Fractions)		9. PROCESSING PROCEDURES	
8. PRODUCT FORMULA		SQ. IN.	

TOTAL		(Percent must total 100%)	
10. NAME AND ADDRESS OF FIRM (Below and between dots)		11. SIGNATURE OF APPLICANT OR AGENT	
		DATE	
		12. SIGNATURE OF INSPECTOR	
		DATE	
		13. CONDITIONS APPLYING TO USE OF LABELS OR DEVICE	

